Diabetes Management with Clinical Decision Support

Introduction

Background Information

25.8 million.

This figure represents the total number of children and adults, who are affected by diabetes in the United States according to the National Diabetes Fact Sheet 2011, (Centers for Disease Control and Prevention [CDC]. National diabetes fact sheet: national estimates and general information on diabetes and pre-diabetes in the United States, 2011. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2011). There are 18.8 million people diagnosed with diabetes and 7.0 million who are undiagnosed which is 8.3% of the U.S. Population and is the seventh leading cause of death in the United States.
The National Diabetes Fact Sheet also states that the percentage of prevalence of diabetes in race and ethnic groups are as follows:

- 7.1% of non-Hispanic whites
- 8.4% of Asian Americans
- 12.6% of non-Hispanic blacks
- 11.8% of Hispanics

Complications associated with those patients diagnosed with diabetes include heart disease and stroke, high blood pressure, blindness, kidney disease, nervous system disease (neuropathy) and amputation (typically of the lower limbs). Based on these statistics, the management of diabetes, in particular, diabetes type 2 is of extreme importance to improve the quality of care, improve patient adherence to treatment plans including prescribed medications, and improve the follow up with labs and results and perform timely foot and eye exams.

Managing a chronic disease such as diabetes requires close follow-up with patients, quick access to the most up-to-date evidence based guidelines and easy access to patient information and their medical record. The Institute of Medicine (IOM) has developed the Six Aims for achieving improvement in healthcare that should be taken into serious consideration when caring for patients, especially those with chronic diseases. The Six Aims for improvement of healthcare are that healthcare must be *safe, effective, patient-centered, timely, efficient,* and *equitable*. (http://www.ihi.org/knowledge/Pages/ImprovementStories/AcrosstheChasmSixAimsforChangingtheHealthCareSystem.aspx).

Implementing IOM's Six Aims in conjunction with clinical decision making for the management of diabetes and other chronic diseases, is a daunting task, but one that must be done and done well. There are some uncertainties as to how this can be achieved effectively while maintaining and promoting a good doctor-patient relationship and improving the quality of patient care.

Making the most informed clinical decision for diabetes continues to be a challenge because of the many different evidence based guidelines and protocols available that have been created and

developed by federal agencies and organizations. The Centers for Disease Control and Prevention (CDC), The United States Preventive Services Task Force (USPSTF), the American Diabetes Association (ADA) and the Physician Consortium for Performance Improvement (PCPI) are just a few of the federal agencies and organizations who are dedicated to the research and update of these guidelines made available to healthcare stakeholders involved in the care of the patient.

Some of the guidelines and recommendations for the management of diabetes take into consideration factors such as age, race and ethnicity, risk factors for diabetes such as medical history, family history and social history, in order to determine the most appropriate treatment plan for a patient. Every patient is different, and therefore the treatment plan must be as well. There are many challenges of knowing how to treat the patient with the most appropriate plan. Some of the challenges and contributing factors, specifically for diabetes are: Is the patient's medication list updated? Have the correct labs been ordered? Have the labs been ordered timely? Are the lab results back? If the labs results are abnormal, what are the next steps? When was the patient's last foot exam and eye exam? Is the patient in compliance with the treatment plan?

One final question: How can the provider and the patient stay abreast of all of the items mentioned above without the use of a clinical decision support system?

In an ambulatory setting the use of a clinical decision support system is of significant importance as those patients diagnosed and undiagnosed with diabetes is growing at a rapid pace and we must have aggressive tools in place to control its destructive path.

Stakeholders, Goals and Objectives

Using the worksheet suggested by the HIMSS CDSGuide, the following stakeholders, their roles, clinical goals and clinical objectives are as follows as it relates to the existing clinical decision support model that I am adding to:

Stakeholders(s) (Title)	**Role**	**High Level Clinical Goals**	**Clinical Objectives**
Chief Medical Officer	Proponent, clinical thought leader	Disease specific management and prevention	• Improve lab follow-up • Improve patient medication prescription adherence
Chief Information Officer	Proponent, technology thought leader	Effective and appropriate use of clinical technology	• Improve efficient use of EHR for clinical documentation
Chief Quality Officer	Proponent, general quality leader	Disease specific management and adherence to IOM Six Aims	• Reduce redundant and duplicate lab orders • Improve patient compliance to treatment plans
Champion Physician	Detractor	• Disease specific management • Complete and accurate clinical	• Improve patient participation in disease management (self-foot exams, diet and exercise)

		documentation	• Improve accuracy of clinical documentation

Information System Inventory

To take full advantage of the functionality of the clinical decision support system that I am enhancing, the following information system inventory will provide the most benefits to the clinician and staff using the system. The infrastructure recommended is flexible depending on the size of the practice and the number of users. It is best to define the roles of each user and how they will use the CDSS prior to building the inventory. The CDSS is designed to operate effectively using multiple workstations in a wireless environment for ease of use and mobility. It will also allow the use of mobile devices such as the iPhone, iPad and tablet PC if suitable to the workflow. The quality and age of the devices must be the compatible with the latest release of windows software. Clinicians will have remote use and access to the CDSS through their electronic health record application while the patient will have the ability to test their blood sugar glucose at home which will automatically update the patient's electronic health record with the results. The results will populate and update the CDSS rules engine in real-time.

There are also a number of other medical devices that are compatible with the use of the CDSS to help facilitate the rules engine for pertinent alerts and reminders to the clinician. Some of the devices include, but are not limited to:

- Patient Kiosk – this will allow for patient check-in and demographic updates entered by the patient
- Patient Portal – the portal will allow the patient to view their medical record securely and make limited changes from home or anywhere they have access to the internet
- Vitals Device – this will aid in reducing errors when entering a patient's height, weight, blood pressure, etc. the data will be captured electronically through this device and will automatically populate the patient's electronic health record thus promoting CDSS recommendations.

The reliability and speed of the hardware and software is detrimental to the success of the CDSS's effectiveness and ease of use. Therefore an IT team may be needed to ensure the reliability of the system, monitor maintenance updates and reduce the downtime of the system. It is also of extreme importance to integrate any disparate systems in use by the practice to have a highly efficient CDSS. This includes having the ability to seamlessly collect data from other systems such as the hospital systems, laboratories, medical devices, etc. Without the full integration of health information exchange and interoperability, the full potential of the CDSS application cannot be realized.

Intervention Selection and Workflow Opportunities

As mentioned earlier, managing a chronic disease such as diabetes poses many challenges in effectively and efficiently caring for the patient. Those guidelines and protocols provided by the federal agencies and organizations play a part in improving care for the diabetic patient. The

CDSS program that I am familiar with is in its infancy so therefore I would like to add two interventions into the already existing program:

a. Time-based Checking and Protocol/Pathway Support (Osheroff, Pifer, Teich, Sittig, Jenders, 2005)
b. Reactive Alerts and Reminders (Osheroff, et al. 2005)

I have chosen these two interventions because of their ease of use when integrated within an electronic health record (EHR). For example: lab follow-up, examinations of the eyes and foot, diet and exercise, and more are all crucial elements to the care of the diabetic patient and should be met and tracked in a timely manner.

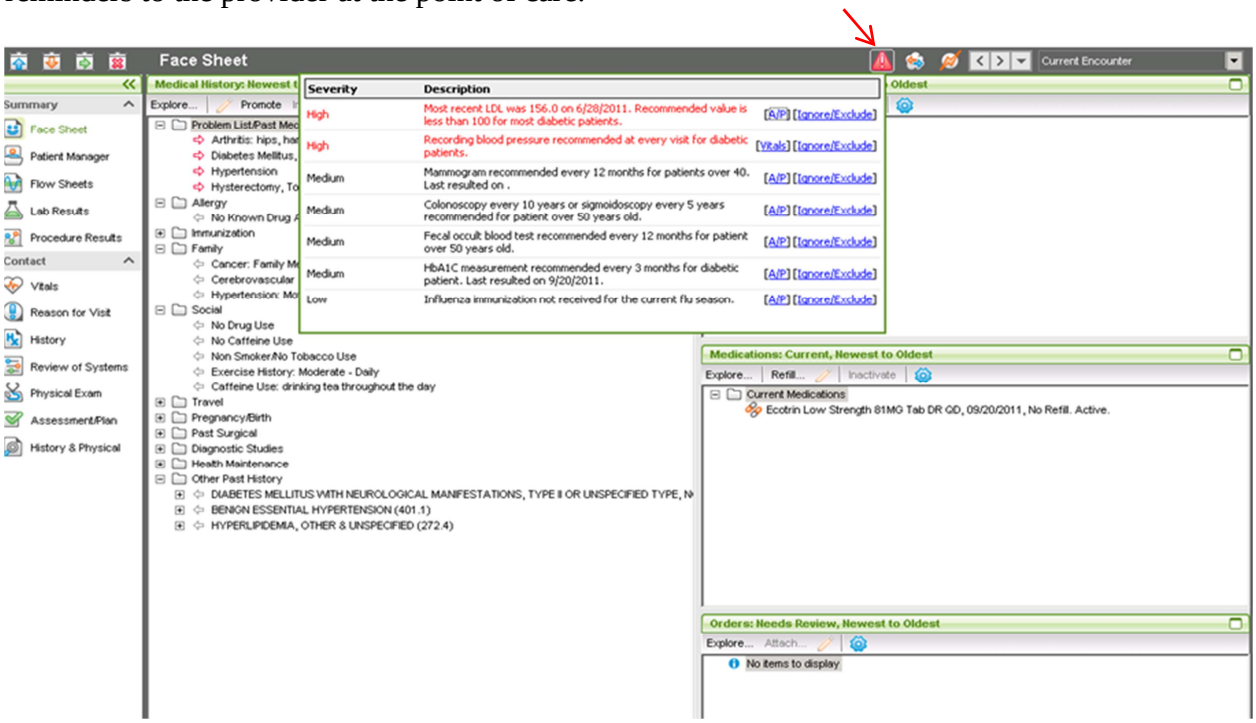
The ***time-based checking and protocol/pathway support*** intervention can provide flow sheets to indicate to the provider: when the lab was performed last and what the result was; when was the patient' last foot and eye exam. Where the CDS intervention is displayed will make all the difference in how useful it is to the provider. To help mitigate alert fatigue, or limit the search for this information, a flow sheet will be available to the clinician the moment the patient's record has been accessed. This will inform the clinician immediately the latest details about the patient's medical status. To allow for flexibility, each user of the system can decide which part of the patient's record they would like to see upon opening the patient's chart.

The ***reactive alerts and reminders*** are easy to use and access giving providers an immediate indicator of items that need action regarding the patient's care. The alerts and reminders can be tied directly to the time-based checking and protocol/pathway support. For example, based on the suggested protocol and pathway for disease management, an alert pop-up can display as another enforcement to remind the clinician or the clinician's staff to take action. The action will be documented in the patient's record and captured as discrete information for later reporting if desired. The alerts and reminders are easy to address by users who are authorized to do so.

These two interventions will mostly affect the provider's documented office visit at the point of care. Implementing the CDS interventions at the point of care will provide more efficient use in the workflow of documentation at the time of notification. The clinician will receive real-time pertinent clinical recommendations as information is entered and updated in the patient's record. The alerts and reminders are easy to address and will provide an easy access to patient information of overdue items such as labs, exams, etc. The time-based checking protocols and pathway support intervention can be displayed as part of the patient's dashboard which allows the provider to view those pertinent items that should be addressed with the patient during the office visit. ***See Figure 1.1.***

Through interviewing healthcare stakeholders such as existing users of an EHR system (Jim Morrow, MD, personal communication, July 26, 2012) the feedback received was to have the alerts at the point of care while the patient was still in the office and even in the exam room. In the event that something was missed or overdue for a patient such as an overdue lab, it could be addressed immediately during that visit the patient for better compliance and improved care.

Figure 1.1 – The screen below shows the CDSS displaying real-time recommended alerts and reminders to the provider at the point of care.



Change Management Plan

Implementing change can bring with it frustration, fear of failure and especially for some clinicians, the lack of desire not to change the way they diagnose and treat patients.

With the increased adoption of electronic health records and CDSS, change is inevitable. To address the change, a plan must be put into place to help mitigate these feelings. The plan that I will use includes some of the following from the Clinical Decision Support in Electronic Prescribing: Recommendations and an Action Plan: Report of the Joint Clinical Decision Support Workgroup (Teich, MD, Jonathan M., Osheroff, MD, Jerome A., Pifer, MD, Eric A., Sittig, PhD, Dean F., Jenders, MD, MS, Robert A.)

a. Develop a CDSS committee
b. Define priorities and baselines
c. Consider workflows of all stakeholders
d. Educate stakeholders of the CDSS knowledge database through training webinars and online learning
e. Address all concerns of all stakeholders
f. Agree upon a back-up plan to address system downtime and unintended consequences
g. Meet regularly to flush out workflows and changes to any of the above items

System Design

Design Document and Architecture

Please refer to the link with the worksheet provided by the HIMSS CDS Guide. It provides the step by step process of the existing CDSS that I will be adding to. (http://www.himss.org/content/files/Worksheet2_2_2012_Osheroff_CDS.pdf). In addition, the system architecture currently uses XML/XSLT along with HL7 and ANSI X12 for interoperability with disparate systems mentioned previously such as the hospital system, laboratories, pharmacies, and medical devices. There is a central data repository in the CDSS knowledge database which provides a rule-based engine generating recommended alerts and reminders to the users of the system at the point-of-care.

The document will be created all at once and would be designed and updated through surveys, meetings, and feedback from the healthcare stakeholders involved in the process including those who are also considered to be detractors to the new CDSS and its enhancements. The same committee would be also responsible for maintaining the design document and meeting regularly to address the concerns and any potential need for change. This will be an ongoing effort to produce the most efficient and effective system. By creating the document at once, it will allow for quicker turnaround time for those things that may require change during and after implementation.

Intervention (Content) Specification

The decision logic and information content delivered with the CDSS will come from multiple resources in particular the American Diabetes Association (ADA) as well as the AHRQ (Agency for Healthcare Research and Quality) and other sources. The evidence based guidelines provided will satisfy the goals and objectives for the management of diabetes type II through the intervention types mentioned previously: Time-based checking and protocol pathway support and alerts and reminders. By using the evidence based guidelines from the ADA and AHRQ, the CDS program will optimize effectiveness by "providing clear and practical recommendations, linking advice to action opportunities." (Osheroff, Pifer, Teich, Sittig, Jenders, 2005)

Because I am adding on to an existing CDS program currently in early development, I will use the same logic already in place but expound upon its functionality by providing improvements to the quality and effectiveness of patient outcomes and physician performance and use.

The CDSS program will incorporate the performance measures provided by the Physician Consortium for Performance Improvement quality measures. I believe that using these particular measures will gain the buy-in from those physicians that may not otherwise feel compelled to use the CDS program simply because these measures have been developed by physicians for physicians which may prove to be more favorable instead of enforcing federal initiative measures.

Presently the only input from the user that is required is to address those alerts and reminders that show as URGENT and overdue so as to avoid alert fatigue. The CDS intervention will also provide physicians with highly suggested protocols or order sets for the treatment of diabetes

type II and will require that they make an appropriate selection displayed or they can override the suggestion but may be required to put in a reason why for auditing purposes depending on the severity of the recommendation. The recommendations will be agreed upon by the healthcare stakeholder committee and upheld by the committee. Feedback from those outside of the committee will be addressed and determined how best to fit the desired workflow.

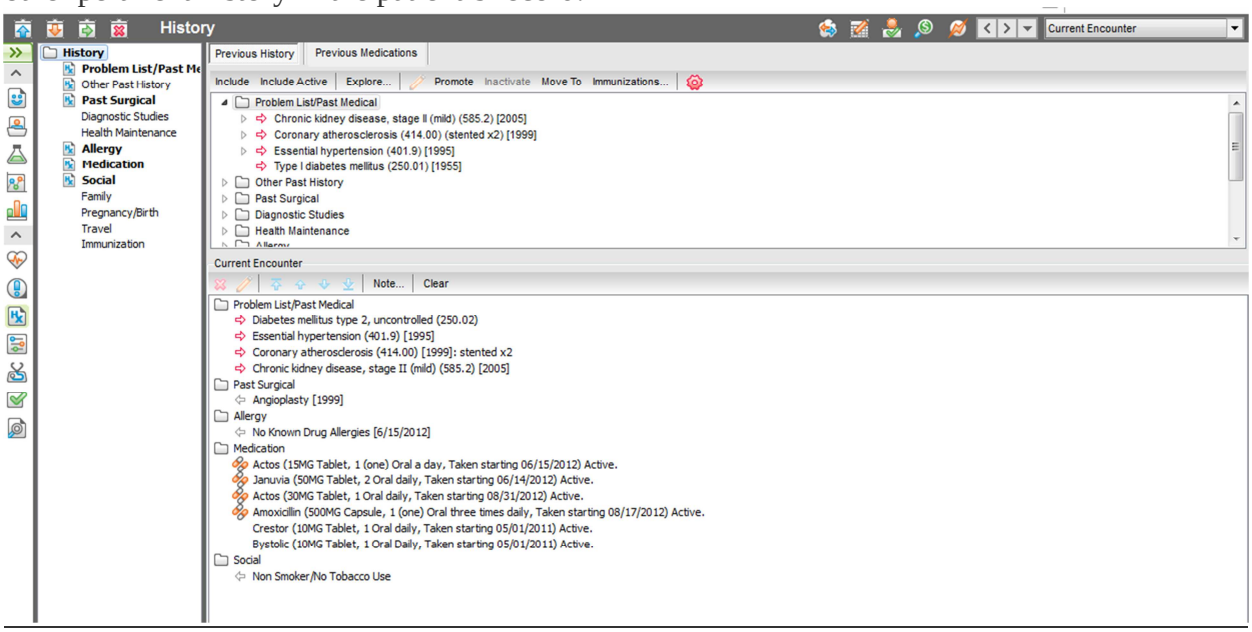
To maintain the content provided in the CDS program as with any other updates with the electronic health record system, any updates for content or for new guidelines will come in the form of electronic release notes and will offer an automatic update when new guidelines are available or allow the users to select when they want to update any new content. Again, this process will be agreed upon by the stakeholder committee to determine how best to address any new updates and if they are a good fit and conducive to the workflow.

User Interface

The user interface is designed to be user-friendly for the clinician and their staff. Through normal documentation from the patient and staff such as medication updates, past medical, family and social history, bi-directional lab interface with send and receive orders and results and patient pharmacy updates, the rules engine will automatically pool the data and generate recommended alerts and reminders based on the patient data entered. Therefore it is important to clearly define the workflow roles prior to implementation to ensure the patient data is entered into the EHR record the same way every time. This will produce more accurate protocols, alerts and reminders.

When the clinician or patient has entered the information into the patient's electronic health record (***see Figure 1.2***), the information will be seamlessly sent to the CDSS knowledge database to generate the most recent and up to date guidelines and will display and change as the patient's data changes during a visit or anytime that patient's record has been updated. This process is seamless to the end user and will provide minimal distraction during the documentation process.

Figure 1.2: Input to the System – the screen below shows the where data will be entered by the clinician such as problem list/past medical, past surgical, medication history, social history and other pertinent history in the patient's record.



The CDS tool will generate recommendations real-time to provide the clinicians with the most accurate information for improved patient safety, outcomes and results. The clinicians will have the opportunity to "ignore or exclude" any recommendations at their discretion. However, depending on the practice policy a reason may be required at that time. (***See Figure 1.1***)

Knowledge Engineering

Currently the CDSS uses measures from Healthcare Effectiveness Data and Information Set (HEDIS) and Meaningful Use (MU) and Physician Quality Reporting System (PQRS) from the DiagnosisOne™ platform. As an enhancement to the existing CDSS, included will be measures from the PCPI that will be integrated into the CDSS knowledge database. As the content is updated in the knowledge database, the updates will be pushed real-time to the CDSS program directly to the EHR into the patient's record. DiagnosisOne™ was selected because it uses service oriented architecture (SOA) and will provide easy integration between the CDSS and the EHR and other disparate systems. Business analysts were used to determine the best CDSS knowledge database to be used in conjunction with the existing electronic health record.

The stakeholder committee will decide on the best alternatives to display to the clinicians when recommendations are made by the CDSS. However, the development team and business analysts will remain in weekly contact with those same teams at DiagnosisOne™ to address and ensure when and if system design and content changes are available or coming. This will allow for proactive management of any system changes and to inform the committee if necessary. There will also be some automated updates that will minimally interfere with workflow activities and provide for the most accurate and timely clinical information to the provider. When new updates have been made, the users will receive an indicator when logging into the CDSS. They

will also receive memos via email, text and memos to ensure they are fully aware of any changes.

Evaluation

Evaluation and analysis of the CDSS must be ongoing. The stakeholder committee will use tracking and log files to determine how often a user "ignored" or "excluded" a recommendation. To best evaluate the CDSS, I will use the multi-dimensional model as defined in "Improving Outcomes with Clinical Decision Support: An Implementer's Guide (Osheroff, et al. 2005). The evaluation model lists the following for evaluation and the process must be repeated back to #2:

1. Create interventions
2. Verify and Validate (if errors found, skip to #5)
3. Monitor and Measure (if errors found, skip to #5)
4. Evaluate Effectiveness
5. Modify and Maintain

Determining when the alert was "fired" and "ignored" during the documentation process will be important in the verification process to determine if the program was built right for the workflow desired. By creating a "use and usability issues log" it will give immediate feedback as to why and how often clinicians found issue with the CDSS and if it was used. The log can be used to go back and modify and maintain and in some cases go back to step #1 (Osheroff, et al.2005). If the log shows poor use of the intervention, then new interventions may be needed. One way sensitivity analysis plays an integral role in validating the CDSS. Changing one parameter of the intervention may show how much it affects the outcome. This is a time-consuming process but is one that must be incorporated into the evaluation process. If the interventions aren't being used, the CDSS becomes useless.

This example shows the importance for the committee to meet monthly and in some cases weekly until the evaluation process is acceptable to all stakeholders using the system.

Discussion

As an add-on to an existing CDSS, it is ready for implementation however that doesn't mean that it is ready for acceptance. There are still limitations to the program since it is in its infancy and thorough evaluation will continue well after implementation is completed.

Some of the shortcomings of the model in the current release is the clinician is not yet able to make any changes to the interventions on their own. They are only authorized to "ignore or exclude" an intervention. The ability to customize and create new interventions will be available in a future release of the CDSS.

It is strongly recommended that a CDSS be implemented into a practice that is technology savvy and not afraid to embrace change. Although this may seem highly unlikely, there are some clinicians who are ready to embrace and embark on the journey to better patient care thorugh the use of technology.

The key assumptions made throughout the project were minimal since the project was previously scoped it is already in existence. The platform used and some of it functionality was already in place but has room for improvement such as the display of recommendations and where they display. Some future enhancements or extensions of my CDSS model would include flexibility for “on-demand” customization of interventions functionality. Other future functionality would include the ability to quickly access the desired guidelines and quickly import guidelines directly into the CDSS with minimal effort and at the user level.

Despite the benefits listed in research and literature for implementation of a clinical decision support system, many clinicians and staff still don’t see the need. The CDSS is not meant to replace the physician’s knowledge of their thought process but to aid them in making more informed clinical decisions in the care of the patient. If we also implement the Six Aims stated previously in conjunction with CDSS, it may be an easier process to accept rather than looking at it as a replacement of what clinicians take pride in, making the best clinical decisions for the patient.

References

Retrieved from: http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2011.pdf

Retrieved from: http://www.ihi.org/knowledge/Pages/ImprovementStories/AcrosstheChasmSixAimsforChangingtheHealthCareSystem.aspx

Osheroff, Jerome A. (2005). Improving Outcomes with Clinical Decision Support: An Implementer's Guide. 34 – 35

Teich, MD, Jonathan M., Osheroff, MD, Jerome A., Pifer, MD, Eric A., Sittig, Phd, Dean F., Jenders, MD, MS, Robert A. Clinical Decision Support in Electronic Prescribing: Recommendations and an Action Plan: Report of the Joint Clinical Decision Support Workgroup. Journal of the American Medical Informatics Association. Volume 12, Issue 4, July–August 2005, Pages 365–376.